

DANIEL HUBERT, individually and on behalf of	:	Civil Action No. 2:15-cv-01391-MRH
all others similarly situated,	:	
	:	
Plaintiff,	:	
	:	Oral Argument Requested
v.	:	
	:	This Document Relates to:
GENERAL NUTRITION CORPORATION,	:	All Actions
	:	
Defendant.	:	
	:	
(In re: GNC Picamilon/BMPEA Litigation)	:	

Defendant General Nutrition Corporation (“GNC”), by and through its attorneys Amy B. Alderfer, Esquire, Paul K. Leary, Jr., Esquire, and Brett N. Taylor, Esquire, and the law firm Cozen O’Connor, file the following Reply in Support of GNC’s Motion to Dismiss Plaintiffs’ First Amended Consolidated Class Action Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (6), for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted.

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MEMORANDUM OF POINTS AND AUHTORITIES

I. INTRODUCTION

Plaintiffs' Opposition to GNC's Motion to Dismiss is premised on one central argument that is the lynch pin of their entire opposition and, in fact, their entire case: parallel claims. However, despite page after page of case law establishing what parallel claims are and how they are recognized, Plaintiffs fail to ever engage in a meaningful analysis or demonstration of how parallel claims exist here in this case. Instead Plaintiffs offer the basic and unsupported conclusion that they have pleaded parallel claims which survive preemption. To be clear, virtually every argument made in Plaintiffs' Opposition is premised on this argument. Absent a showing of how parallel claims have been pleaded, Plaintiffs' Opposition crumbles like a house of cards.

Moreover, Plaintiffs' claims fail because they are presume that the ingredients at issue here (BMPEA, picamilon, and acadia rigidula) are illegal but cannot pinpoint where this legal determination has been made. The reason being there has been no determination of illegality or safety of the ingredients. To the contrary, there was indirect approval of picamilon as an ingredient (as recently as April 15, 2016) as exemplified by the Certificates of Free Sale¹ that were issued involving two of the products which are the subject of this action.

II. PLAINTIFFS' CLAIMS SHOULD BE DISMISSED

A. Plaintiffs Lack Standing to Pursue Their Claims.

The essence of Plaintiffs' First Amended Complaint ("FAC") is that by selling picamilon and BMPEA, GNC endangered the health of its consumers and raised issues of consumer safety.

¹ Knowing that the Certificates of Free Sale are contrary to Plaintiffs' allegations regarding illegality, Plaintiffs attempt to exclude these damaging documents by requesting that the Court not consider them in their opposition to GNC's Request for Judicial Notice. However, for the reasons explained in GNC's Reply in support of its Request for Judicial Notice filed concurrently herewith, the Certificates of Free Sale are properly before the Court.

(FAC ¶ 98.) In fact, the FAC is replete with allegations that these ingredients endangered Plaintiff's health. Specifically, Plaintiffs allege that:

- Para. 5: GNC failed to disclose “material facts about the dangers of *ingesting* picamilon, BMPEA, and acacia rigidula. It took these actions at the expense of *consumer safety* . . .” (Emphasis added)
- Para 6: “Plaintiffs are consumers who were hoodwinked into purchasing supplements with mislabeled and *dangerous ingredients*.” Plaintiffs claim they would not have purchased these supplements “had GNC disclosed that they contained mislabeled ingredients *which pose serious health risks* . . .” (Emphasis added)
- Para 38: “GNC has long known, these are substances which pose *unique health dangers* . . (Emphasis added)
- Para 47: “GNC otherwise failed to inform consumers that picamilon is a *dangerous, synthetic stimulant*.” (Emphasis added)
- Para 98: GNC sold products to Plaintiffs and statewide class members “*endangering their health*.” (Emphasis added)
- Para. 102: “[T]he dietary supplements are *dangerous instrumentalities* . . .” (Emphasis added)

For whatever reason, Plaintiffs fail to allege that they actually consumed the “dangerous instrumentalities.” Instead, Plaintiffs shift the focus of the standing argument to economic injury. Their efforts fail for two reasons.

First, the essence of the FAC, as is shown above, is the physical harm posed by these products and the inability to even allege that any member of the class consumed the products is fatal. In their Complaint, Plaintiffs must “clearly ... allege facts demonstrating” each element of

standing. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016), as revised (May 24, 2016).

Plaintiffs have not done so here.

Second, even if the Court were to accept the Plaintiffs' claims of economic injury as sufficient to theoretically establish standing despite the primary thrust of the FAC, here, Plaintiffs fail to sufficiently plead an injury-in-fact as they fail to allege purchase of the products after the date the FDA issued its warning letters on the ingredients. In other words, at the time of the purchases complained of in the FAC, the FDA had not acted in any way to even question the use of the ingredients. Or, put differently, at the time Plaintiffs are alleged to have purchased products containing the complained of ingredients, GNC had no notice that the ingredients were not lawfully offered for sale. Plaintiffs lack standing for this additional reason. Absent standing, Plaintiffs cannot move forward with their case and it can be dismissed in its entirety and with prejudice on this basis alone.

B. Plaintiffs' Fail to Plead Parallel Claims and their Claims are Therefore Preempted.

In an incredible show of bravado, Plaintiff assert that their claims "easily escape preemption" because their suit is based on parallel claims. As is set forth below, Plaintiffs offer this Court nothing in terms of any analysis demonstrating how this is in fact the case.

There is a recognized *narrow* exception to express preemption for claims that "'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Establishing liability via a parallel claim is "more difficult than it would be in a typical product liability case." *White*, 818 F. Supp. 2d at 1037. As stated in the moving papers, there is a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009); *See also In re Medtronic, Inc., Sprint Fidelis Leads*

Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir.2010); *McLaughlin v. Bayer Corp.*, No. CV 14-7315, 2016 WL 1161578, at *5 (E.D. Pa. Mar. 22, 2016). “For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA. *Riley v. Cordis Corp.*, 625 F. Supp. 2d at 777 (D. Minn. 2009). Put slightly differently, to state a “parallel” claim, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the product; (2) the violation of an *identical* state-law duty; and (3) that the predicate federal violation caused his or her injuries. *See, e.g., Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488-89 (7th Cir. 2005); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013); *White v. Stryker*, 818 F. Supp. 2d 1032, 1039-40 (W.D. KY. 2011). Moreover, a plaintiff must plead more than non-specific regulations as a basis for a parallel claim; “a greater level of specificity in pleading a parallel claim” is required. *See Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495-96 (W.D. Pa. 2012).

Cases like *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation (Medtronic Leads I)*, 592 F. Supp. 2d 1147,1158 (D. Minn. 2009), *aff’d*, *Medtronic Leads II*, 623 F.3d 1200 and *Wolicki-Gables* recognize that courts cannot simply accept supposedly parallel claims without closely examining whether the plaintiff’s state law cause of action actually imposes duties that are genuinely equivalent to the duties imposed by federal law. Plaintiffs here fail to satisfy this demanding standard.

Plaintiffs’ opposition recites page after page of case law on parallel claims but never demonstrate how the sixteen (16) individual state laws, from ten (ten) different states pleaded by Plaintiffs are genuinely equivalent to the duties imposed by federal law.² Yet nowhere does

² . The FAC pleaded violations of the state laws of ten different states: Arkansas, California, Florida, Iowa, Michigan, Minnesota, New York, New Hampshire, Pennsylvania, and Texas.

Plaintiffs' opposition make any effort to demonstrate that the language of those state statutes is identical to Federal law. Instead, Plaintiffs conclude pages of case citations by stating:

"Plaintiffs' Complaint asserts precisely such parallel claims under state consumer protection and false advertising acts, unfair competition law, Little Food Acts, breach of warranty, negligent misrepresentation, and unjust enrichment—all of which escape preemption under Section 343-1." (Opp. at 20 of 35.)

Saying something is true does not make it so. Plaintiffs have utterly failed to demonstrate how any of the state laws they are suing on are identical to Federal law. As such, Plaintiffs have failed to plead parallel claims and GNC's motion to dismiss on the basis of express preemption must be granted.

Moreover, it is clear that Plaintiffs' claims are expressly preempted. The FDCA's primary focus is ensuring that drugs are "safe, effective and not misbranded," which the FDA ensures by enforcing the regulations. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (2d Cir.1990). The FDCA's text and the FDCA's legislative history make clear that Congress intended the government, not private parties, to have exclusive responsibility for enforcing the provisions of the FDCA. *See Caudill Seed & Warehouse Co., Inc. v. Jarrow Formulas, Inc.*, No. 3:13-CV-00082-CRS, 2015 WL 10943828, at *16 (W.D. Ky. Oct. 29, 2015)(Finding California's unfair competition claim had been preempted and noting that "the claim in substance is about an FDCA violation, which has been preempted by Congress' occupation of the field.")

Based on the forgoing, GNC's motion to dismiss should be granted, with prejudice.

C. Plaintiffs' Claims are Impliedly Preempted and They May Not Enforce the FDCA.

Plaintiffs' FAC fails for the additional reason that it is impliedly preempted. In a futile attempt to defeat implied preemption, Plaintiffs try to impose the narrowest reading of *Buckman* possible on this court, arguing that it does not apply on the grounds that there is no "fraud" on

the FDA alleged here. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Such a limited reading unnecessarily limits *Buckman* and ignores its progeny.

Buckman's relevance for this case is in its recognition that Congress prohibited private parties from enforcing the FDCA. *See Buckman*, 531 U.S. at 349, n.4 (noting "FDCA leaves no doubt it is Federal Government rather than private litigants who are authorized to file suit for noncompliance [of its] provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.' 21 U.S.C. § 337(a)."). It is the basis of the claim asserted that is relevant, not the state-law label plaintiffs attach to it. In *Buckman*, plaintiffs alleged a state-law fraud claim. The Supreme Court recognized the claim as a "fraud-on-the-agency" claim that existed "solely by virtue of federal law." *Buckman*, 531 U.S. at 353. The same holds true here.

Plaintiffs label their claims as various state law claims, but the FAC reveals that the basis of each of these claims is solely federal law - just as the plaintiffs in *Buckman* could not state their claim without reference to the FDCA, plaintiffs here cannot do so either. In fact, the situations are one-and-the-same and both fall within the purview of FDA's enforcement authority and the prohibition against private rights of action in 21 U.S.C. § 337(a).

Plaintiffs cite to *ThermoLife Intern, LLC v. Gaspari Nutrition Inc.*, 2016 WL 1460171 (9th Cir. Apr. 14, 2016) and *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228 (2014) for the proposition that Plaintiffs' claims are not preempted. However, this case is distinguishable. First, *ThermoLife* and *POM* involved allegations of the Lanham Act and Arizona's common law, neither of which are alleged by Plaintiffs in their operative complaint. Moreover, *POM* noted the fact that FDCA enacted an express pre-emption provision with respect to state laws addressing food and beverage misbranding. *See POM Wonderful LLC*, 134 S.Ct. at 2237. Additionally,

POM did not involve pre-emption, but rather preclusion of one federal statute by the provisions of another federal statute. *Id.* at 2236. Second, The *ThermoLife* Court found that the FDCA did not impliedly preempt the claims because the state-law paralleled the federal-law duty. Here, however, Plaintiffs have not properly pled allegations of parallel claims in their FAC.

D. Plaintiffs Have Failed to Allege a Determination of Illegality of the Ingredients.

Plaintiffs' claims fail because they are predicated on the notion that the ingredients are illegal but cannot point to where this determination has been made. For Plaintiffs to prevail on their claims, they need to show a determination of illegality or safety with regard to the ingredients. However, there has been no formal final agency action by the FDA that any of the ingredients were illegal. The only evidence, other than conclusory allegations, that Plaintiffs can point to is the Welch declaration. However a declaration of an FDA employee of her opinion on an issue is far from an agency determination. State law claims do not permit a plaintiff to make the determination that something is illegal under the FDA. Without such a determination by the FDA, Plaintiffs' claims fail.

E. Agency Approval

Citing *Altria Grp., Inc. v. Good*, 555 U.S. 70 (2008), Plaintiffs argue that agency non enforcement is not the same as "a policy of approval." (Opp. at 24.) The problem here is that Plaintiffs fail to give credit to the fact there is more than just "agency non enforcement" here. Just months before Dr. Welch's declaration was procured, the FDA signed a Certificate of Free Sale for two of the products at issue indicating that those products were freely marketed in the United States. Unlike the Welch declaration, which was merely an opinion of someone employed by the FDA and not agency action, the Certificates of Free Sale bear the office seal of and are formal pronouncement of the U.S. the Department of Health and Human Services. As to

Plaintiffs' argument that parallel claims do not depend on FDCA violations, as set forth above Plaintiffs have failed to demonstrate the existence of viable parallel claims in this case.

Moreover, as is set forth in GNC's moving papers, allowing warning letters sent to others to serve as final agency action would deprive GNC of its due process rights. Plaintiffs' rejoinder to this is that final agency action is not required for this Court to adjudicate parallel claims. This argument fails because, as demonstrated above, Plaintiffs have failed to articulate viable parallel claims. Because of this, Plaintiffs' entire argument in this regard crumbles.

III. CONCLUSION

For the reasons set forth above and in GNC's moving papers, GNC respectfully requests that this Court grant its Motion to Dismiss Plaintiffs' FAC in its entirety and with prejudice.

Dated: July 15, 2016

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